

REMARKS

Status of the Claims

No amendments to the claims have been made. Claims 1-11 are still pending.

Obviousness-type double patenting rejection

Claims 1-11 were rejected over U.S. Patent 6,592,883 (SN: 09/640,528) under obviousness-type double patenting grounds. However, the applicants have already filed a terminal disclaimer over this application on 27 May 2003 (which was filed concurrently with the IDS which the examiner marked as being considered in her office action).

If the examiner needs another copy of this terminal disclaimer, it requested that the examiner telephone the undersigned to obtain this copy.

Stray papers being returned to PTO

Attached to the applicants' copy of the office action was an Information Disclosure Statement for SN: 09/946,658 (Inventor: Vijay Kumar). These papers appear to have been inadvertently included in the mailing as they are not part of the present application's prosecution history and as such are being returned to the PTO for appropriate handling.

35 U.S.C. 112, first paragraph rejection

Claim 8 was rejected as being enabling for "substances effective against acne" but not astringents or anti-microbially effective substances. As both of these ingredients are contemplated in the specification (which includes the claims as originally filed) - see also page 17, lines 11-12, it is not clear why the examiner believes that one of ordinary skill in the art would not be able to add either of these ingredients to the preparation of claim 1.

The initial burden is on the examiner to show that the invention is not enabled as claimed. The examiner is reminded that the test for enablement is cited within MPEP 2164.01 which states:

"The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: *is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied.* In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The factors for determining undue experimentation are described in MPEP 2164.01(a):

"**There are many factors to be considered** when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". **These factors include, but are not limited to:**

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;

- (D) The level of one of ordinary skill in the art;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)."

There has been no *Wands*-type analysis made; only a conclusionary statement. Therefore, the initial burden for showing lack of enablement has not yet been established.

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment Under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, Washington, D.C. 20231, on the date indicated below:

Date: **8 October 2003**

By: Agata Glinska
Agata Glinska